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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,797	04/26/2007	Bodo Gerold	149459.00002	1514

25207 7590 09/04/2008

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EXAMINER	
PEPITONE, MICHAEL F	

ART UNIT	PAPER NUMBER
1796	

MAIL DATE	DELIVERY MODE
09/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,797	GEROLD ET AL.	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites at least 90 weight-percent of tantalum, which would include values greater than the 10 to 90 weight-percent of marker component in the base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-7, 9, 16, and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Heublein *et al.* (US 2002/0004060), in view of Stinson *et al.* (US 6,340,367).

Regarding claim 1, 5-7, and 16: Heublein *et al.* teaches a biodegradable implant {stent} (¶ 2, 11, 30) comprising 50-98% magnesium, less than 5% of other metals or rare earths such as gold, as well as trace amounts of other additions (¶ 14-16, 30). Heublein *et al.* does not teach 10 to 90 wt% of radiopaque elements [instant claims 1, 7 and 16]; Heublein *et al.* does not teach at least 90% tantalum as the radiopaque marker [instant claims 5-6].

However, Stinson *et al.* teaches an implantable radiopaque marker {radiopaque stent} (1:5-8), wherein the amount of radiopaque element is added at various loading percentages approaching the threshold above which the loading causes unsatisfactory results (3:60-4:7) [instant claims 1, 7 and 16], and that tantalum is used as a stent component [instant claim 5-6] (4:24-26). Heublein *et al.* and Stinson *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of implantable radiopaque marker. At the time of invention a person of ordinary skill in the art would have found it obvious to have used tantalum as a stent component (4:24-25), and optimized the amount of radiopaque element, as taught by Stinson *et al.* in the invention of Heublein *et al.*, and would have been motivated to do so since Stinson *et al.* suggests that the radiopacity capability is proportional to the linear attenuation coefficient and the thickness of the absorber material (3:13-15), and is an equivalent alternative means of providing an implantable radiopaque marker.

Regarding claim 2-3: Heublein *et al.* teaches a magnesium alloy [instant claims 2-3] (¶ 13-22).

Regarding claims 9 and 18: Heublein *et al.* Heublein *et al.* teaches trace amounts of other additives, specifically 0.28-0.5% manganese (¶ 21, 30).

Claims 11, and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heublein *et al.* (US 2002/0004060), in view of Stinson *et al.* (US 6,340,367).

Regarding claims 11, 13-14: Heublein *et al.* teaches a biodegradable implant {stent, occluder} [instant claim 14] (¶ 2, 11, 29-31, 33-37) comprising 50-98% magnesium [instant claim 13], less than 5% of other metals or rare earths such as gold, as well as trace amounts of other additions (¶ 14-16, 30). Heublein *et al.* does not teach 10 to 90 wt% of radiopaque elements [instant claim 11].

However, Stinson *et al.* teaches an implantable radiopaque marker {radiopaque stent} (1:5-8), wherein the amount of radiopaque element is added at various loading percentages approaching the threshold above which the loading causes unsatisfactory results (3:60-4:7) [instant claim 11]. Heublein *et al.* and Stinson *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of implantable radiopaque marker. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the amount of radiopaque element, as taught by Stinson *et al.* in the invention of Heublein *et al.*, and would have been motivated to do so since Stinson *et al.* suggests that the radiopacity capability is proportional to the linear attenuation coefficient and the thickness of the

absorber material (3:13-15), and is an equivalent alternative means of providing an implantable radiopaque marker.

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heublein *et al.* (US 2002/0004060), in view of Stinson *et al.* (US 6,340,367).

Regarding claims 12 and 15: Heublein *et al.* teaches a biodegradable implant {stent, occluder} (¶ 2, 11, 29-31, 33-37) comprising 50-98% magnesium [instant claim 15], less than 5% of other metals or rare earths such as gold, as well as trace amounts of other additions (¶ 14-16, 30). Heublein *et al.* does not teach 10 to 90 wt% of radiopaque elements [instant claim 12].

However, Stinson *et al.* teaches an implantable radiopaque marker {radiopaque stent} (1:5-8), wherein the amount of radiopaque element is added at various loading percentages approaching the threshold above which the loading causes unsatisfactory results (3:60-4:7) [instant claim 12]. Heublein *et al.* and Stinson *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of implantable radiopaque marker. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the amount of radiopaque element, as taught by Stinson *et al.* in the invention of Heublein *et al.*, and would have been motivated to do so since Stinson *et al.* suggests that the radiopacity capability is proportional to the linear attenuation coefficient and the thickness of the absorber material (3:13-15), and is an equivalent alternative means of providing an implantable radiopaque marker.

Claims 4, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heublein *et al.* (US 2002/0004060), in view of Stinson *et al.* (US 6,340,367), as applied to claim 1 above, and in further view of Chandrasekaran *et al.* (US 2003/0153971).

Regarding claims 4, 10, and 19: Heublein *et al.* and Stinson *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 1]. Heublein *et al.* does not teach a composite having a biodegradable polymer as the base component [instant claim 4], comprising hyaluronic acid, chitosan, and polylactides [instant claims 10 and 19].

However, Chandrasekaran *et al.* teaches a biodegradable, metallic alloy medical implant {stent} (¶ 1, 9-10) comprising biodegradable polymers including polylactides, chitosan, and hyaluronic acid (¶ 60-61). Heublein *et al.* and Chandrasekaran *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of degradable, metallic alloy medical implants {stents}. At the time of invention a person of ordinary skill in the art would have found it obvious to have utilized hyaluronic acid, chitosan, and polylactides, as taught by Chandrasekaran *et al.* in the invention of Heublein *et al.*, and would have been motivated to do so since Chandrasekaran *et al.* suggests that such biodegradable polymers provide an enhanced ability to customize the mechanical properties of the stent and time dependent changes associated with lumen healing, as well as the ability to provide a controlled release of therapeutic agents (¶ 36 and 41), and is an equivalent alternative means of providing degradable, metallic alloy medical implants {stents}.

Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heublein *et al.* (US 2002/0004060), in view of Stinson *et al.* (US 6,340,367), as applied to claim 1 above, and in further view of Meyer-Lindenberg *et al.* (US 2004/0241036).

Regarding claims 8 and 17: Heublein *et al.* and Stinson *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 1]. Heublein *et al.* does not teach yttrium as a component in the marker.

However, Meyer-Lindenberg *et al.* teaches a degradable, magnesium alloy medical implant (¶ 1, 7-8) comprising yttrium in an amount of 0.01-7 wt% (¶ 10-14). Heublein *et al.* and Meyer-Lindenberg *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of degradable, magnesium alloy medical implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have utilized yttrium, as taught by Meyer-Lindenberg *et al.* in the invention of Heublein *et al.*, and would have been motivated to do so since Meyer-Lindenberg *et al.* suggests that the admixture of yttrium to the magnesium alloy leads to grain refinement, producing slow, continuous and well controlled degradation (¶ 7-8, 17 and 30), and is an equivalent alternative means of providing degradable, magnesium alloy medical implants.

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Response to Arguments

Applicant's arguments filed 6/6/08 have been fully considered but they are not persuasive. The rejection of claims 1-14 over Heublein *et al.* (US 2002/0004060), Stinson *et al.*

(US 6,340,367), and Meyer-Lindenberg *et al.* (US 2004/0241036) is maintained for reason of record and following response.

Heublein *et al.* (US '060) teaches a biodegradable implant {stent} (¶ 2, 11, 30) comprising 50-98% magnesium, less than 5% of other metals or rare earths such as gold, as well as trace amounts of other additions (¶ 14-16, 30).

Stinson *et al.* (US '367) teaches an implantable radiopaque marker {radiopaque stent} (1:5-8), wherein the amount of radiopaque element is added at various loading percentages approaching the threshold above which the loading causes unsatisfactory results (3:60-4:7), wherein the thickness of the radiopaque material is about 20 microns to 500 microns (4:27-56). The radiopaque material may disperse into the body when in vivo (5:49-62). Stinson *et al.* (US '367) clearly discloses that the marker can be anchored to an endoprosthesis {stent}, thereby preventing the marker from releasing from the implantable endoprosthesis {corresponding to a permanent radiopaque marker} (6:5-24).

Stinson *et al.* (US '367) discloses a radiopaque marker having a thickness of about 20 microns to about 500 microns (4:27-56; 16:8-16). The weight of the coating could be calculated via the volume of the coating and density of the marker. Additionally, Stinson *et al.* (US '367) discloses biosorable markers in application 08/904,951 {corresponding to Stinson (US 6,174,330)}, wherein a coating thickness of about 20 microns to 500 microns of radiopaque material corresponds to about 1 wt% to about 80wt% of radiopaque material [Stinson (US '330); 6:18-34].

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Meyer-Lindenberg *et al.* (US '036) magnesium alloy medical implant (¶ 1, 7-8) comprising yttrium in an amount of 0.01-7 wt% (¶ 10-14), corresponding to less than or equal to 15 wt% of ytrrium as a component of the marker.

In response to applicant's argument that Meyer-Lindenberg *et al.* (US '036) does not disclose or suggest using yttrium as a radiopaque substance, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
21-August-08

/Marc S. Zimmer/
Primary Examiner, Art Unit 1796